STATUTORY INSTRUMENTS

2019 No. 1385

EXITING THE EUROPEAN UNION
CONSUMER PROTECTION
MEDICINES

The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

Made - - - - 23rd October 2019

Coming into force in accordance with regulation 1

The Secretary of State makes the following Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 [M1].

In accordance with paragraph 1(3) of Schedule 7 to the European Union (Withdrawal) Act 2018, a draft of these Regulations has been laid before and approved by a resolution of each House of Parliament.

Marginal Citations

M1 2018 c. 16.

Citation and commencement

1. These Regulations may be cited as the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 and come into force immediately before exit day [M2].

Commencement Information

I1 Reg. 1 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M2 "Exit day" is defined in section 20 of the European Union (Withdrawal) Act 2018.

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

2. The Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 [M3] are amended in accordance with Schedule 1.

Commencement Information

I2 Reg. 2 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M3 S.I. 2019/775.

Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

3. The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 [M4] are amended in accordance with Schedule 2.

Commencement Information

I3 Reg. 3 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M4 S.I. 2019/791.

Signed by authority of the Secretary of State for Health and Social Care.

Blackwood
Parliamentary Under-Secretary of State,
Department of Health and Social Care

SCHEDULE 1

Regulation 2

Amendment of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019

Interpretation

1. In this Schedule, "the 2012 Regulations" means the Human Medicines Regulations 2012 [M5].

Commencement Information

I4 Sch. 1 para. 1 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M5 S.I. 2012/1916; relevant amendments were made by S.I. 2019/775.

PROSPECTIVE

Amendment of regulation 15 (amendment of regulation 18 of the 2012 Regulations – wholesale dealing in medicinal products)

[F1]**2.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

PROSPECTIVE

Amendment of regulation 17 (amendment of regulation 19 of the 2012 Regulations – exemptions from requirement for wholesale dealer's licence)

[F1]**3.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

PROSPECTIVE

Amendment of regulation 47 (amendment of regulation 48 of the 2012 Regulations – application of Part 5)

[F1]**4.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

PROSPECTIVE

Amendment of regulation 56 (substitution of regulation 51 of the 2012 Regulations - applications relating to generic medicinal products)

F1**5.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

PROSPECTIVE

Amendment of regulation 58 (amendment of regulation 53 of the 2012 Regulations - applications relating to similar biological medicinal products)

F1**6.** . . . . . .

F1 Sch. 1 paras. 2-6 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(a)**

Amendment of regulation 63 (amendment of Schedule 11 to the 2012 Regulations – advice and representations)

7.—(1) Regulation 63 is amended as follows.

(2) For paragraph (2)(a)(ii) substitute—

"(ii) at the end insert—

"and;

(d) a proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.";".

(3) After paragraph (2) insert—

"(2A) In paragraph 2 (requirement to consult the appropriate committee), after sub-paragraph (2), insert—

"(2A) The licensing authority must consult the appropriate committee if the authority proposes to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.".

(2B) In paragraph 3 (exceptions to requirement to consult)—

(a) in sub-paragraph (1), after "traditional herbal registration" insert " , or to a proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation, "; and

(b) in sub-paragraph (1)(a), after "determined", insert " or the decision to be made ".

(2C) In paragraph 5 (provisional opinion against authorisation)—

(a) after sub-paragraph (2), insert—

"(2A) If the appropriate committee is consulted under paragraph 2(2A), it may give a provisional opinion that it may be unable to advise the licensing authority to decide that the orphan criteria are met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation."; and

(b) in sub-paragraph (3), after "grant or renewal", insert " , the applicant intending to demonstrate that the orphan criteria are met in relation to a medicinal product, ".

(2D) In paragraph 10 (decision of licensing authority)—

(a) omit the "or" at the end of sub-paragraph (1)(b); and

(b) at the end of sub-paragraph (1)(c) insert—

"; or

(d) decide whether to proceed with its proposal to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation,".".

(4) For paragraph (3) substitute—

"(3) In paragraph 12 (licensing authority decisions in other cases)—

(a) in sub-paragraph (1), insert " , parallel import licence " after " UK marketing authorisation " in each place it appears;

(b) in sub-paragraph (5), insert " , licence " after " the authorisation "; and

(c) after sub-paragraph (4), insert—

"(4A) This paragraph also applies if, having been consulted under paragraph 2(2A), the appropriate committee has not given a provisional opinion in the terms described in paragraph 5(2A) and the licensing authority proposes to decide, against that committee's advice, that the orphan criteria are not met in relation to a medicinal product which is the subject of an application for the grant of a UK marketing authorisation.".".

(5) After paragraph (3) insert—

"(3A) After Part 1 insert—

"PART 1A

Paediatric Decisions

Application of this Part

13A. This Part applies to a proposed decision by the licensing authority—

(a) to refuse to agree a paediatric investigation plan (including a waiver or deferral proposed to be included in that plan), or to agree such a plan otherwise than in accordance with the request for agreement;

(b) to refuse to agree a modification to a paediatric investigation plan (including a waiver or deferral which is, or is proposed to be, included in that plan), or to agree such a modification otherwise than in accordance with the request for the modification;

(c) to impose, revoke or refuse to grant a waiver of the obligation under regulation 50A(3) to provide to the licensing authority the results of all

studies performed, and details of all information collected, in compliance with an agreed paediatric investigation plan; or

(d) to revoke a waiver which was agreed as part of an agreed paediatric investigation plan.

Opportunity to make representations

13B.—(1) If the licensing authority proposes to make a decision to which this Part applies, the licensing authority must notify the person to whom the proposed decision would be addressed ("the applicant").

(2) The applicant may, by notice in writing to the licensing authority, request the opportunity to make written or oral representations to the appropriate committee.

(3) The applicant must make the request before the end of the period of 28 days beginning with the day on which the notification is given or such longer period as the licensing authority may allow.

(4) The licensing authority must inform the appropriate committee of the applicant's request.

Written representations

13C.—(1) If the applicant requests the opportunity to make written representations, the applicant must provide the appropriate committee with those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of 28 days beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 13B.

(2) The appropriate committee may at the request of the applicant extend the period mentioned in sub-paragraph (1) up to a maximum of 56 days beginning with the date of the request under paragraph 13B.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Oral representations

13D.—(1) If the applicant requests the opportunity to make oral representations, the applicant must provide the appropriate committee with a written summary of those representations and any documents on which the applicant wishes to rely in support of them—

(a) before the end of the period of 28 days beginning with the date of the request; or

(b) before the end of such shorter period as the licensing authority may specify in the notification under paragraph 13B.

(2) The appropriate committee may, at the request of the applicant, extend the period mentioned in sub-paragraph (1) up to a maximum of 56 days beginning with the date of the request under paragraph 13B.

(3) The applicant may submit additional representations or documents after the end of the period for doing so only with the permission of the appropriate committee.

(4) After receiving the summary and any other documents provided under this paragraph, the appropriate committee must arrange for the applicant to make oral representations at a hearing before the committee.

(5) The appropriate committee must—

(a) take the representations made under this paragraph into account; and

(b) report its findings and advice to the licensing authority together with the reasons for that advice.

Other decisions of the appropriate committee

13E.—(1) This paragraph applies if the applicant—

(a) requests the opportunity to make written representations, but fails to make those representations within the period for doing so; or

(b) requests the opportunity to make oral representations, but—

(i) fails to provide a summary of those representations or the documents in support of them within the period for doing so, or

(ii) fails to make oral representations at a hearing before the appropriate committee.

(2) The appropriate committee must notify the licensing authority of that fact.

Decision of licensing authority

13F.—(1) The licensing authority must decide whether to proceed with its proposed decision—

(a) if the applicant requested the opportunity to make written or oral representations, after receiving the appropriate committee's report under paragraph 13C or 13D or notification under paragraph 13E; or

(b) if the applicant did not request the opportunity to make written or oral representations, after the expiry of the period of time for notifying a request for that opportunity.

(2) If the appropriate committee gives a report under paragraph 13C or 13D, the licensing authority must take that into account in making its decision.

(3) The licensing authority must notify the applicant of—

(a) its decision; and

(b) any advice given to it by the appropriate committee and the reasons for that advice.

Right to review after paragraph 13F notification

13G.—(1) This paragraph applies if the licensing authority notifies the applicant of its decision under paragraph 13F.

(2) The applicant may notify the licensing authority in writing that the applicant wishes the licensing authority to submit the decision to review upon oral representations.

(3) The applicant must give the notification before the end of the period of 28 days beginning with the day on which the notification is given to the applicant under paragraph 13F or such longer period as the licensing authority may allow.

(4) The review must be conducted in accordance with Schedule 5.

(5) This paragraph does not apply if the applicant has not made any representations in accordance with paragraph 13C or 13D.".".

Commencement Information

I5 Sch. 1 para. 7 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 139 (amendment of regulation 177 of the 2012 Regulations – application of Part 11 (pharmacovigilance) and interpretation)

F2**8.** . . . . . .

F2 Sch. 1 para. 8 omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(b)**

Amendment of Schedule 6 (insertion of Schedule 12A into the 2012 Regulations)

9. In Schedule 6, in Part 8 of inserted Schedule 12A to the 2012 Regulations (periodic safety update reports), in paragraph 27 (format of periodic safety update reports)—

(a) re-number the existing paragraph as sub-paragraph (1) of paragraph 27; and

(b) insert at the end—

"(2) In this paragraph, "signal evaluation" means the process of further evaluating a validated signal taking into account all available evidence, to determine whether there are new risks causally associated with the active substance or medicinal product, or whether known risks have changed, and that process—

(a) may include non-clinical and clinical data; and

(b) must be as comprehensive as possible regarding the sources of information used for that process.".

Commencement Information

I6 Sch. 1 para. 9 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of Schedule 7 (insertion of Schedule 33A into the 2012 Regulations)

10.—(1) Schedule 7 is amended as follows.

(2) In paragraph 5 of inserted Schedule 33A to the 2012 Regulations (list of countries with equivalent regulatory standards as to the manufacturing of active substances on exit day), after paragraph (e) insert—

"(ea) Republic of Korea;".

F3(3) . . . . . .

F4(4) . . . . . .

F3 Sch. 1 para. 10(3) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(c)**

F4 Sch. 1 para. 10(4) omitted (31.12.2020 immediately before IP completion day) by virtue of The Human Medicines (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1488), reg. 1, **Sch. 3 para. 1(c)**

Commencement Information

I7 Sch. 1 para. 10 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

SCHEDULE 2

Regulation 3

Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019

Interpretation

1. In this Schedule, "the 2002 Regulations" means the Medical Devices Regulations 2002 M6.

Commencement Information

I8 Sch. 2 para. 1 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M6 S.I. 2002/618; relevant amendments were made by S.I. 2019/791.

Amendment of regulation 3 (amendment of Part I of the 2002 Regulations)

2.—(1) Regulation 3 is amended as follows.

(2) In paragraph (6), in inserted regulation 3A of the 2002 Regulations (designated standard)—

(a) for paragraph (1), substitute—

"(1) In [F5Parts II, III and IV] of these Regulations, a "designated standard" means—

(a) a technical specification which is—

(i) adopted by a recognised standardisation body, for repeated or continuous application with which compliance is not compulsory; and

(ii) designated by the Secretary of State by publishing a reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate; or

(b) a monograph of the European Pharmacopoeia (in particular on surgical sutures and on the interaction between medicinal products and materials used in devices containing medicinal products) which has been published in the Official Journal of the European Union.";

(b) in paragraph (3)(b), for "(CENLAC)" substitute, " (CENELEC) ";

(c) for paragraph (8), substitute—

"(8) In this regulation—

(a) a reference to a "device" is a reference to a medical device or its accessory or an in vitro diagnostic medical device or its accessory to which these Regulations apply;

(b) a reference to "the European Pharmacopoeia" is a reference to the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia."
M7

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F6(3) . . . . . .

F5 Words in Sch. 2 para. 2(2)(a) substituted (9.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(a)(i)**

F6 Sch. 2 para. 2(3) omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(a)(ii)**

Commencement Information

I9 Sch. 2 para. 2 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M7 Council of Europe (ETS No. 050), Strasbourg, 22.07.1964.

Amendment of regulation 4 (amendment of Part II of the 2002 Regulations)

3. In regulation 4(4), in inserted regulation 7A of the 2002 Regulations (registration of persons placing general medical devices on the market), after paragraph (2), insert—

"(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.".

Commencement Information

I10 Sch. 2 para. 3 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 5 (amendment of Part III of the 2002 Regulations)

4. In regulation 5(3), in inserted regulation 21A of the 2002 Regulations (registration of persons placing active implantable medical devices on the market) after paragraph (2), insert—

"(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.".

Commencement Information

I11 Sch. 2 para. 4 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment of regulation 6 (amendment of Part IV of the 2002 Regulations)

5. In regulation 6(3), in inserted regulation 33A of the 2002 Regulations (registration etc. of persons placing in vitro diagnostic medical devices on the market) after paragraph (2), insert—

"(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.".

Commencement Information

I12 Sch. 2 para. 5 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 7 (amendment of Part V of the 2002 Regulations)

F7 6. . . . . . .

F7 Sch. 2 para. 6 omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(b)**

Amendment of regulation 8 (amendment of Part VI of the 2002 Regulations)

7. In regulation 8, for paragraph (4), substitute—

"(4) In regulation 55 [M8] (fees payable in connection with the designation etc. of EC conformity assessment bodies)—

(a) in the heading omit "EC";

(b) in paragraph (1), for "an EC CAB" substitute " a CAB ";

(c) in paragraph (3)—

(i) for "an EC CAB" substitute " a CAB ";

(ii) for "the Mutual Recognition Agreements" substitute " a mutual recognition agreement ".".

Commencement Information

I13 Sch. 2 para. 7 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M8 2018 c. 16.

Amendment of regulation 9 (amendment of Part VII of the 2002 Regulations)

8. In regulation 9(3) (amendment of regulation 60 of the 2002 Regulations), for sub-paragraph (d), substitute—

"(d) in paragraph (4)—

(i) for "an authorised representative of a manufacturer of a device" substitute " a UK responsible person ";

(ii) for "the single authorised representative of the manufacturer" substitute " a UK responsible person ".".

Commencement Information

I14 Sch. 2 para. 8 in force at 31.12.2020 immediately before IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

PROSPECTIVE

Amendment of regulation 10 (insertion of Part VIII into the 2002 Regulations)

F8 9. . . . . . .

F8 Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(c)**

PROSPECTIVE

Amendment of regulation 11 (insertion of new Part IX into the 2002 Regulations)

F8 10. . . . . . .

F8 Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(c)**

PROSPECTIVE

Amendment of regulation 12 (new Schedules to the 2002 Regulations)

F8 11. . . . . . .

F8 Sch. 2 paras. 9-11 omitted (9.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), regs. 1(2), **4(2)(c)**

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of, and paragraph 21 of Schedule 7 to, the European Union (Withdrawal) Act 2018 (c. 16) ("the Withdrawal Act") in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c) and (d) of the Withdrawal Act) arising from the withdrawal of the UK from the European Union.

Regulation 2 and Schedule 1 amend the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/775) ("the Medicines Exit Regulations"). The Medicines Exit Regulations amend the Human Medicines Regulations 2012 (S.I. 2012/1916) ("the Principal Medicines Regulations").

Paragraphs 2 and 3 amend regulations 15 and 17 of the Medicines Exit Regulations (amendment of regulations 18 and 19 of the Principal Medicines Regulations) to ensure that the requirements for a wholesale dealer's licence apply to hospitals importing human medicinal products directly from a country on an approved list, including for their own use (but not to those persons importing a medicine from such a country purely for administration to themselves or a member of their household).

Paragraph 4 amends regulation 47 of the Medicines Exit Regulations to ensure that the definition of "EU reference medicinal product" in regulation 48 of the Principal Medicines Regulations includes a medicinal product which was the subject of a marketing authorisation granted by the European Commission under Regulation (EC) No. 726/2004 which had been cancelled before exit day on grounds not relating to safety, quality or efficacy. Reference medicinal products are products in relation to which there was a full set of data supporting the application for the marketing authorisation for the product, and reliance may be placed on part of that data by subsequent applicants, for example applicants for marketing authorisations for generic versions of innovative products.

Paragraph 6 amends regulation 58 of the Medicines Exit Regulations so as to insert some missing words into regulation 53 of the Principal Medicines Regulations (biosimilar applications) relating to the time period for which biological reference medicinal products have to have been authorised before an abridged application may be made in reliance on the data supporting such reference products.

Paragraph 7 ensures that the amendments made to Schedule 11 to the Principal Medicines Regulations by regulation 63 of the Medicines Exit Regulations accommodate the process for seeking advice and making representations in relation to the new decisions conferred on the licensing authority by the Medicines Exit Regulations in relation to orphan (rare disease) medicines and paediatric medicines.

Paragraph 8 amends regulation 139(6) of the Medicines Exit Regulations (amendment of regulation 177 of the Principal Medicines Regulations) to include a definition of "signal" in relation to pharmacovigilance activities.

Paragraph 9 amends Schedule 6 to the Medicines Exit Regulations (insertion of Schedule 12A into the Principal Medicines Regulations) to provide for a definition of "signal evaluation" in paragraph 27 of inserted Schedule 12A in relation to periodic safety update reports.

Paragraph 10 amends Schedule 7 to the Medicines Exit Regulations (new Schedule 33A to the Principal Medicines Regulations - transitional provision in relation to EU Exit). The amendments—

(a) add the Republic of Korea to the list of countries with equivalent regulatory standards as to the manufacturing of active substances on exit day;

(b) ensure that the temporary exemption as to the location of an appropriately qualified person for pharmacovigilance (QPPV) applies to a holder of a UK marketing authorisation or traditional herbal registration granted before exit day, in respect of all UK marketing authorisations or registrations they hold for which there is the same QPPV; and

(c) provide a temporary exemption, subject to specified conditions, regarding the obligation to maintain and make available on request of the licensing authority a UK pharmacovigilance system master file covering all medicinal products for which the holder obtained a UK marketing authorisation.

Regulation 3 and Schedule 2 amend the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791) ("the Devices Exit Regulations"). The Devices Exit Regulations amend the Medical Devices Regulations 2002 (S.I. 2002/618) ("the Principal Devices Regulations").

Paragraph 2 makes minor amendments to regulation 3 of the Devices Exit Regulations, in particular to ensure that monographs of the European Pharmacopoeia, insofar as they relate to medical devices, are included as designated standards (i.e. standards which serve the same purpose as EU harmonised standards and which, if followed, will lead to the device being deemed to meet certain legislative requirements).

Paragraphs 3, 4 and 5 respectively make minor amendments to regulations 7A, 21A and 33A (inserted into the Principal Devices Regulations) to ensure that information provided by manufacturers, as part of the registration obligation, is updated if the information changes after the initial registration.

Paragraphs 6, 7 and 8 make minor amendments to the Devices Exit Regulations.

Paragraphs 9 and 10 make minor amendments to various regulations inserted into the Principal Devices Regulations by the Devices Exit Regulations. In particular these amendments ensure that devices which will be subject to the regulatory regime for the first time are required to comply with certain 'common specifications'.

Paragraph 11 makes minor amendments to Schedules 19 (technical documentation on post-market surveillance for in vitro diagnostic medical devices) and 24 (conformity assessment based on a quality management system) inserted into the Principal Devices Regulations.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sectors is foreseen.

Status:
This version of this Instrument contains provisions that are prospective.

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.